REMARKS

In the Office Action, the disclosure is objected to; claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting; and claims 1-45 are rejected under 35 U.S.C. §102 or, in the alternative, under 35 U.S.C. §103 as obvious over the European Patent No. 0951915A2. Applicants believe that the objections and rejections should be withdrawn at least for the reasons set forth below.

With respect to the disclosure objection, Applicants believe that the Patent Office's position is improper. In this regard, the Patent Office asserts that the section titled "BRIEF DESCRIPTION OF THE DRAWINGS" is missing. However, on page 7, at lines 11-22 of the specification, the section titled "BRIEF DESCRIPTION OF THE FIGURES" is provided. This should satisfy the Patent Office's request. Therefore, the disclosure objection should be withdrawn in view of same.

In the Office Action, claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-42 of copending Application No. 10/327,264. Applicants believe that this rejection is improper. Indeed, the subject matter as defined by claims 1-42 of the copending application recites solutions that require, in part, a solution part with a pH ranging from 7.0 to about 12.0, such as by adjustment with a pH stabilizer. This is distinguishable from a dialysis solution with both first and second acidic solution parts that are admixed to form a ready-to-use solution as required by the claims of the present invention. Thus, Applicants believe that the provisional obviousness-type double patenting rejection should be withdrawn for at least these reasons.

In the Office Action, claims 1-45 are rejected under 35 U.S.C. §102 or, in the alternative, under 35 U.S.C. §103 as obvious over the European Patent No. 0951915A2. Applicants believe that this rejection is improper and thus should be withdrawn. Claim 1 recites a dialysis solution that includes a first acidic solution including a dextrose concentrate; and a second acidic solution including a buffer concentrate wherein the first acidic solution and the second acidic solution are admixed to form a ready-to-use dialysis solution. Claim 8 recites a two part peritoneal dialysis solution that includes a first part including an acidic concentrate that includes dextrose; and a second part including a lactate-based buffer concentrate having a pH of less than 7.0 wherein the first part and the second part are admixed prior to infusion into a patient.

Claim 17 recites a two part peritoneal dialysis solution that includes a first part housed in a first structure. The first part includes an acidic dextrose concentrate. The two part peritoneal dialysis solution further includes a second part housed in a second structure, the second part includes an acidic buffer concentrate where the first part and the second part are separately sterilized and admixed to form a ready-to-use peritoneal dialysis solution. Claim 24 recites a method of producing a dialysis solution. The method includes formulating an acidic concentrate and a buffer concentrate having a pH of less than 7.0 wherein the acidic concentrate at least includes dextrose; separately sterilizing the acidic concentrate and the buffer concentrate; and mixing the acidic concentrate and the buffer concentrate. Claim 30 recites a method of modifying a standard dialysis solution. The method includes formulating two or more solution parts of the standard dialysis solution wherein the solution parts at least include a dextrose concentrate and a buffer concentrate; separately sterilizing the dextrose concentrate and the buffer concentrate at a pH of less than 7.0; and mixing the dextrose concentrate and the buffer concentrate to produce a modified standard dialysis solution. Claim 40 recites a method of providing dialysis to a patient. The method includes mixing an acidic dextrose concentrate and an acidic buffer solution to form a ready-to-use dialysis solution wherein the acidic dextrose concentrate and the acidic buffer concentrate are separately sterilized prior to mixing; and using the ready-to-use dialysis solution during dialysis.

The present invention provides dialysis solutions with enhanced biocompatibility. In general, separately formulated and sterilized solution parts are combined to form a ready-to-use solution. The dialysis solutions of the present invention include a first acidic solution part and a second acidic solution part. The first acidic solution part at least includes a dextrose concentrate wherein the second acidic solution part includes a buffer concentrate, such as a lactate-based buffer. See, Specification, page 9, lines 9-15.

Applicants believe that the EP0951915 A2 reference is distinguishable from the claimed invention. At a minimum, nowhere does this reference disclose or suggest a dialysis solution that is formulated from two acidic solution parts where a first solution part includes dextrose and the second solution part includes a buffer concentrate, such as a lactate-based concentrate. At most, this reference provides a dialysis solution with a single acidic solution part. Indeed, the European patent reference provides that a first of two solution parts has a pH that is as high as 8.5. See, EP095915 A2, page 3, paragraph 19. Clearly, one skilled in the art would not consider

this pH to be acidic in value and thus fall outside the claimed invention that requires both first and second acidic solution parts as previously discussed. Moreover, dependent claims 4, 12, 23, 29, and 44 further recite a pH less than about 5.5, such as from about 5.0 to about 5.5, in the buffer concentrate that can include lactate where the buffer concentrate can be mixed with an acidic dextrose concentrate to form a ready-to-use dialysis solution. Based on at least these reasons, Applicants believe that the EP0915915 A2 reference is distinguishable from the claimed invention. Therefore, Applicants do not believe that this reference anticipates or renders obvious claims 1-45 contrary to the Patent Office's position.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30, 142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

Dated: November 30, 2004